UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,137	01/19/2005	Kenichi Yamashita	2005_0047A	2521

513 7590 06/18/2008

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
POHNERT, STEVEN C	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
06/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attachment to Advisory

Continuation of box 11:

The amendment has canceled claim 2 thus overcoming the claim objection.

The double patenting rejection has been overcome as 10/527987 has been abandoned.

The response further asserts that claim the 102 of Wolinsky does not anticipate instant claims 1 and 4. The response asserts that Wolinsky teaches hybridization and flow cytometric analysis, which is not the invention of claims 1 and 4. The response asserts this is clear as claims 1 and 4 require at least 2 solutions is passed through a microchannel and this limitation is not taught by Wolinsky. This argument has been thoroughly reviewed but is not considered persuasive as the claims require passing a solution containing (comprsing) (1) specimen molecules and a (2) solution containing fluorescent probes. Thus a single solution that comprises a specimen and a solution with a fluorescent probes comprises the solution that is being passed through the microflow channel as the claims do not preclude pre-mixing. Thus the method taught by Wolinsky anticipates the claims.

The response further asserts that method of Wolinsky results in turbulent flow not the laminar flow that is claimed. First, MPEP 716.01(c) makes clear that "The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success,

solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Here, the statement the method of Wolinsky results in turbulent flow not the laminar flow that is claimed must be supported by evidence, not argument.

This should not be construed as an invitation for providing evidence. As further stated in the MPEP 716.01 regarding the timely submission of evidence:

A) Timeliness.

Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:

(1) prior to a final rejection,

(2) before appeal in an application not having a final rejection, or

(3) after final rejection and submitted

(i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or

(ii) with a satisfactory showing under 37 CFR 1.116(b) or 37

CFR 1.195, or

(iii) under 37 CFR 1.129(a).

The response further asserts that Wolinksy's method does not result in a change in diffusion coefficient. In response to applicant's argument that the references fail to

show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Wolinksy's method does not result in a change in diffusion coefficient are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus the method of Wolinsky does detect the diffusion of the hybridized probe complex with specimen relative to the non-hybridized probes.

The response further asserts "selectively promoting diffusion" is taught by the specification contrary to the Office action of 2/22/2008. These arguments have been thoroughly reviewed but are not considered persuasive as the cited section of the specification teach, " diffusion can be selectively accelerated." Thus the specification is teaching how diffusion can selectively be accelerated not defining a term. Further the use of the "can" suggests this is an embodiment and not limiting.

The response further asserts that Wolinksy's calibration curve is different than the calibration curve of the instant specification as the instant invention allows for quantitative detection. The specification does not set forth a limiting definition of quantitative analysis and Wolinsky's method allows for the detection of the presence or absence of the probe molecule complex. Wolinsky thus teaches quantitative detection.

The response further asserts that the calibration curve of the instant invention cannot be used for calibration of instruments. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the calibration curve of the instant invention

cannot be used for calibration of instruments) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The response further asserts that the combination of Wolinsky and Chee do not render the instant claims obvious. The response re-asserts that Wolinksy does no teach selective diffusion, this argument has been address previous in this advisory action.

The response asserts that one of skill in the art could not combine the teachings of Wolinksy and Chee because Chee is directed to comparing analyte data to calibration curves to determine the amount of analyte that is present. The response asserts this is different than determining the degree of diffusion of the instant invention. This argument has been thoroughly reviewed but is not considered persuasive as the rejection relies on Wolinsky teaches determining the degree of diffusion of a specimen probe complex and probe molecules. The response thus agrees that Chee teaches a calibration curve and determining the amount. Thus the combination is obvious.

The response further asserts that Chee's method requires the use of solid phase carriers that are dispersed into a solution and that probes and carriers are fixed in Chee's methods. These arguments have been thoroughly reviewed but are not considered persuasive as Chee is being referenced for teaching of calibration curves and thus arguments to Chee's solid carriers are moot.

The response further asserts that the claimed method has overcome the difficulties associated with hybridization prior to analysis as taught by Chee. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., hybridization prior to analysis as taught by Chee) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims require the formation of a complex, which in the art of nucleic acid is hybridization. Further the claims due not exclude hybridization prior to analysis, but a solution comprising two components the specimen molecules and a solution containing a fluorescent probe molecules. Thus Wolinsky teaches a solution containing specimen molecules and probes.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634